

Amendment/Reply

Applicant: Thomas M. Soukup et al.

Serial No.: 10/752,466

Filed: January 6, 2004

Docket No.: H583.104.102

Title: STEERABLE STYLET

REMARKS

This Amendment/Reply accompanies the Request for Continued Examination (RCE) 37 CFR 1.114 and is in reply to the Final Office Action mailed April 13, 2010. Claims 60, 61 and 63-99 were rejected. With this Response, claims 60, 73 and 80 have been amended. Claims 60, 61 and 63-99 remain pending in the application and are presented for reconsideration and allowance.

Claim Rejections under 35 U.S.C. § 112

The Examiner rejected claims 60, 61, and 63-99 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. With this response, Applicant has amended claim 60 and 80 to remove the phrase “without intervention from the operator,” which was identified by the Examiner as unclear. Because the cited language is now removed, it is believed that the objection is overcome.

In view of the above, claims 60, 61, and 63-99 are believed to be in form for allowance. Therefore, Applicant respectfully requests that rejections to these claims under 35 U.S.C. § 112, second paragraph, be reconsidered, and that the rejections be removed and these claims be allowed.

Claim Rejections under 35 U.S.C. § 103

The Examiner rejected claims 60-64, 66, 77-84, 86 and 97-99 under 35 U.S.C. § 103(a) as being unpatentable over the Cookston et al. U.S. Patent No. 6,132,390 in view of the Lundquist et al. U.S. Patent No. 6,033,378.

The Examiner rejected claims 66 and 85 under 35 U.S.C. § 103(a) as being unpatentable over the Cookston et al. U.S. Patent No. 6,132,390 in view of the Lundquist et al. U.S. Patent No. 6,033,378 and further in view of the Erickson et al. U.S. Patent No. 5,755,695.

The Examiner rejected claims 67-74, 76, 87-94 and 96 under 35 U.S.C. § 103(a) as being unpatentable over the Cookston et al. U.S. Patent No. 6,132,390 in view of the Lundquist et al.

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U.S. Patent No. 6,033,378 and further in view of the Rosenman et al. U.S. Patent Application Publication No. 2003/0229386.

The Examiner rejected claims 75 and 95 under 35 U.S.C. § 103(a) as being unpatentable over the Cookston et al. U.S. Patent No. 6,132,390 in view of the Lundquist et al. U.S. Patent No. 6,033,378 and further in view of the Hata et al. U.S. Patent No. 6,611,720.

It is believed that the amended claims are in condition for allowance.

As amended, claim 60 is a steerable stylet, including a stylet wire with a distal region defining a plurality of notches, and a proximal end portion spaced apart from the distal region. The stylet wire has a breaking stress force. A core wire is at least partially disposed within a lumen defined by the stylet wire, and a distal end portion of the core wire is secured to the stylet wire proximate a distal end portion thereof. An adjustable tensioner mechanism is *within a housing* and operably connected between the proximal end portion of the stylet wire and a proximal end portion of the core wire for applying a relative tension force between the stylet wire and the core wire. A *spring within the housing* and operably arranged between the adjustable tensioner mechanism and the proximal end portion of the core wire for *limiting the tension force applied between the core wire and the stylet wire whenever the adjustable tensioner mechanism is adjusted*. This is neither shown nor suggested in the art of record.

As acknowledged by the Examiner on page 4 of the Office Action, the Cookston reference fails to teach or suggest a spring that is operably arranged between the adjustable tensioner mechanism and the proximal end portion of the core wire. Furthermore, the Cookston reference also fails to teach or suggest such a spring for *limiting the tension force applied between the core wire and the stylet wire whenever the adjustable tensioner mechanism is adjusted*.

As described throughout the specification, and for example on page 11, lines 13-28, the spring limits the tension force and prevents the stylet from failing as a result of excessive force. As an operator activates the handle, thereby adjusting the tensioner mechanism applying a relative tension force between the stylet wire and the core wire, the arrangement of the spring between the adjustable tensioner mechanism and the core wire provides a safely limiter:

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When the stylet handle 28 is activated by moving the sliding mechanism 64 in a distal direction, the stylet wire 24 moves distally, but the core wire 26 is restricted from moving, thus creating a relative tension force separating the core wire 26 from the stylet wire 24. In the event that that activated handle 28 is operated to exert a relative tension force of more than about four lbs. of force, the safety feature of the tension limiting spring 62 starts to open and restricts any further load build-up of force on the proximal end portion 30 of the stylet assembly 22, other than the constant force of the tension limiting spring 62 being extended. Specification, page 11, paragraph [0044].

If an operator applies such force while the stylet is deployed intravascularly, a break can be dangerous. The spring allows an automatic safety mechanism to blunt any excessive force and prevent breakage. It is in place to limit the tension force applied between the core wire and the stylet wire *whenever* the adjustable tensioner mechanism is adjusted.

The Cookston reference fails to teach or suggest such a safety mechanism. The smooth bore (258) cited by the Examiner for a tension limiter, is simply coupled with an adjustable screw (256) and slide block (250) that allows an operator access to use an Allen wrench or similar socket head tool in order to make adjustments to overall tension on a wire (18) (see, column 13, lines 26-31). This does not blunt any excessive force and prevent breakage *whenever* the adjustable tensioner mechanism is adjusted. It can be *optionally* adjusted, but *will not* limit a tension force applied between a core wire and the stylet wire *whenever* an adjustable tensioner mechanism is adjusted.

Similarly deficient is the Lundquist reference now cited by the Examiner. There is simply no teaching or suggestion of a spring arranged to limit the tension force applied between the core wire and the stylet wire *whenever* an adjustable tensioner mechanism is adjusted. The spring relied on by the Examiner in the Lundquist reference -- lead spring (1640) -- is located out at the distal tip of the steering mechanism. Two steering wires (1470 and 1480) are attached at two different locations of the lead spring (1640). By individually adjusting tension on the steering wires (1470 and 1480), by rotating shafts 1520 and 1530, the steering shaft (1650) can be turned to the left or to the right, depending on which is tensioned. There is simply no spring that is placed between an adjustable tensioner mechanism and a core wire. There is no spring

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arranged for limiting the tension force applied between a core wire and a stylet wire whenever the adjustable tensioner mechanism is adjusted.

In any event, to further clarify the claim from the art of record, it is further clarified that the adjustable tensioner mechanism and the spring are contained in a housing. This is not taught or suggested in any of the art of record. As such, claim 60 and claim 80, to which similar amendments are made, are now in condition for allowance.

Therefore, Applicant respectfully requests reconsideration and withdrawal of the 35 U.S.C. § 103(a) rejection to the claims, and requests allowance of these claims.

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CONCLUSION

In view of the above, Applicant respectfully submits that pending claims 60, 61 and 63-99 are in form for allowance and are not taught or suggested by the cited references. Therefore, reconsideration and withdrawal of the rejections and allowance of claims 60, 61 and 63-99 are respectfully requested.

No fees are required under 37 C.F.R. 1.16(h)(i). However, if such fees are required, the Patent Office is hereby authorized to charge Deposit Account No. 50-0471.

Please consider this a Petition for Extension of Time for a sufficient number of months to enter these papers, if appropriate. At any time during the pendency of this application, please charge any additional fees or credit overpayment to Deposit Account No. 500471.

The Examiner is invited to contact the Applicant's representative at the below-listed telephone numbers to facilitate prosecution of this application.

Any inquiry regarding this Amendment/Reply should be directed to Paul P. Kempf at Telephone No. (612) 767-2502, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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Respectfully submitted,

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